# EMBOLIC PROTECTION DEVICE

## Field of the Invention

The present invention relates generally to devices and methods for treating occluded or stenoic blood vessels. More particularly, the present invention relates to devices and methods for delivering or retrieving an embolic protection device from the vasculature of a patient.

## Background of the Invention

Atherosclerosis is a major problem wherein blood vessels become blocked or narrowed. This blockage can result in lack of oxygenation to the heart. It is critical that the heart muscle be well oxygenated so that the blood pumping action of the heart is not impaired.

Occluded or stenotic blood vessels may be treated with a number of medical procedures including, for example, angioplasty and atherectomy. Angioplasty techniques such as percutaneous transluminal angioplasty (PTA) and percutaneous transluminal coronary angioplasty (PTCA) are relatively non-invasive methods of treating a stenotic lesion. These angioplasty techniques typically involve the use of a balloon catheter. The balloon catheter is advanced over a guidewire such that the balloon is positioned adjacent a stenotic lesion. The balloon is then inflated and the restriction in the vessel is opened. During an atherectomy procedure, the stenotic lesion may be mechanically cut away from the blood vessel wall using an atherectomy catheter.

During atherectomy procedures, stenotic debris that is separated from the stenosis may be free to flow within the lumen of the vessel. If this debris enters the circulatory system, it could block other vascular regions including the neural vasculature, or in the

lungs. An occlusion in the neural vasculature may cause a stroke, and an occlusion in the lungs may interfere with the oxygenation of the blood. During angioplasty procedures, stenotic debris may also break loose due to manipulation of the blood vessel. Because of this debris, a number of devices termed embolic protection devices have been developed to filter out this debris.

## Summary of the Invention

The present invention relates generally to devices and methods for treating occluded or stenoic blood vessels. More particularly, the present invention relates to devices and methods for delivering or retrieving an embolic protection device from the vasculature of a patient.

An embodiment of the invention includes a filter retrieval catheter. The filter retrieval catheter may comprise an inner shaft slidably disposed within an outer sheath. The inner shaft may include a proximal end, a mid-region, and a tapered distal end. The distal end may include a tubular member. A guidewire can be adapted to pass through the tubular member of the inner shaft. The guidewire may include an embolic protection device coupled to a distal end thereof.

The outer sheath may further comprise an opening. In addition, a cover sheath may be disposed about the outer sheath, for example over the opening. The cover sheath may further comprise a slot that may allow the guidewire to be disposed therein. Retrieval of the embolic protection device may including shifting the position of the inner shaft relative to the opening in the outer sheath.

Preparation of the retrieval catheter may comprise elimination of air from vacant space between the inner shaft and the outer sheath. Air may be substantially eliminated

from the vacant space by flushing the vacant space with a fluid. Fluid can be additionally flushed through the proximal end of the catheter and through the opening. In addition to the vacant spaces, distant vacant spaces may need to be flushed. According to this embodiment, the tubular member may further comprise a plurality of flush holes.

## Brief Description of the Drawings

Figure 1 is a cross sectional view of a filter retrieval catheter in an arrangement suitable for advancement through the vasculature;

Figure 2 is a cross sectional view of a filter retrieval catheter in an arrangement suitable for removal from the vasculature;

Figure 3 is a side view of an alternate embodiment of an outer sheath further comprising a cover sheath;

Figure 4 is a top view of the cover sheath according an embodiment;

Figure 5 is a cross sectional view for preparation of a filter retrieval catheter according to an embodiment of the invention; and

Figure 6 is an alternate cross sectional view for preparation of a filter retrieval catheter according to an embodiment of the invention.

## Detailed Description of the Invention

The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The detailed description and drawings represent select embodiments and are not intended to be limiting.

Figure 1 is a cross sectional view of a filter retrieval and delivery catheter 10 in an arrangement suitable for advancement through the vasculature. In an embodiment, a

filter retrieval catheter 10 may comprise an inner shaft 12 slidably disposed within an outer sheath 14.

Inner shaft 12 may include a proximal end 16, a mid-region 18, and a distal end 20. Proximal end 16 may comprise an elongate tube. The elongate tube may be comprised of materials including, but not limited to, thermoplastics, high performance engineering resins: fluorinated ethylene propylene (FEP), polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC), polyurethane, polytetrafluoroethylene (PTFE), polyether-ether ketone (PEEK), polyimide, polyamide, polyphenylene sulfide (PPS), polyphenylene oxide (PPO), polysufone, nylon, perfluoro(propyl vinyl ether) (PFA), metals: stainless steel, nickel alloys, nickel-titanium alloys, and combinations thereof.

Proximal end 16 may be held to secure inner shaft 12 relative to outer sheath 14, for example be a lock wire 22. Alternatively, inner shaft 12 may be held in place relative to a guidewire 24. According to this embodiment, movement of guidewire 24 results in substantially similar movement of inner shaft 12. Moreover, movement of either guidewire 24 or inner shaft 12 may occur independently of movement of outer sheath 14.

Mid-region 18 may comprise an opening on each of two opposite ends. The openings may be appropriate for coupling mid-region 18 to proximal end 16 and distal end 20. Mid-region 18 may comprise a polymer or metal, including those listed above. In an exemplary embodiment, mid-region 18 comprises polyethylene.

Distal end 20 may comprise a tubular member 26 having a proximal region 28, a distal region 30, and a lumen 32 extending therethrough. Lumen 32 may be a guidewire lumen adapted for housing guidewire 24. Distal end 20 may comprise polyimide.

Alternatively, distal end 20 may comprise materials similar to those listed above. Tubular member 26 is coupled to mid-region 18. For example, tubular member 26 may be disposed within an opening within mid-region 18 and bend to exit a second opening within mid-region 18. The bend in tubular member 26 when exiting mid-region 18 may define a port 34 that may be disposed at proximal region 28. A tip 36 can be disposed at distal region 30 of tubular member 26. Tip 36 is comprised of generally soft or atraumatic materials. For example, tip 36 may be comprised of materials including polymers. In addition, tip 36 may be comprised of materials similar to those listed above.

Outer sheath 14 may be disposed around inner shaft 12. Outer sheath 14 may be comprised of materials including, but not limited to, metals, alloys, nickel alloys, nickel titanium alloys, polymers, and combinations thereof. Alternatively, outer sheath 14 may be comprised of materials similar to those listed above.

Outer sheath 14 includes a proximal end 38, a distal end 40, and a lumen 42 extending therethrough. Lumen 42 is sized to allow inner shaft 12 to be slidably disposed therein.

Outer sheath 14 may include an opening 44. Opening 44 can be, for example, about 2 inches long. Opening 44 can be, for example, less than about 4 inches long. Opening 44 may further comprise a proximal region 46 and a distal region 48. In an exemplary embodiment, inner shaft 12 is disposed within lumen 42 such that port 34 is disposed substantially proximate opening 44.

Guidewire 24 may further include a proximal end 50 and a distal end 52. An embolic protection device 54, such as a distal protection filter, may be disposed at distal end 52. Embolic protection device 54 is adapted to prevent embolic debris from

travelling away from a treatment site. According to this embodiment, embolic protection device 54 can substantially prevent embolic debris from occluding a blood vessel down stream from a treatment site.

Catheter 10 may be used as a filter retrieval catheter or a filter delivery catheter. When used to retrieve embolic protection device 54, catheter 10 is configured relative to guidewire 24 and inner shaft 12 is configured relative to outer sheath 14. As to configuring catheter 10 relative to guidewire 24, catheter 10 is generally passed over guidewire 24. According to this embodiment, guidewire 24 passes through lumen 32 of tubular member 26, through port 34, and through opening 44. Proximal end 50 of guidewire 24 extends proximally out of outer sheath 14 at opening 44. Distal end 52 of guidewire 24 extends distally out of tip 36 of distal region 30 of inner shaft 12.

When configured for retrieving embolic protection device 54 (or when generally configured for advancing through the vasculature) guidewire 24 may be locked relative to inner shaft, for example by locking wire 22. Moreover, guidewire 24 is generally disposed at a location near distal region 48 of opening 44 (as shown in Figure 1). Disposing guidewire 24 near distal region 48 of opening 44 may be advantageous when using catheter 10 for retrieval. For example, positioning guidewire 24 near distal region 48 during retrieval (or generally during advancement of catheter 10 through the vasculature) makes available space for guidewire 24 to shift (proximally) within opening 44. This feature is important because guidewire 24 and inner shaft 12 may be locked. Thus, allowing space for guidewire 24 to proximally shift may allow movement or shifting of inner shaft 12 relative to sheath 14 (as described in more detail below).

As to configuring inner shaft 12 relative to outer sheath 14, inner shaft 12 may be oriented in a first position (as shown in Figure 1). In the first position, inner shaft 12 is positioned distally within sheath 14 such that at least a portion of tip 36 extends out from outer sheath 14. In an exemplary embodiment, a tapered portion of tip 36 extends out of outer sheath 14 when inner shaft 12 is in the first position. Generally, the first position is appropriate for advancing catheter 10 through the vasculature and provides a generally tapered or atraumatic distal end to catheter 10.

Retrieval of embolic protection device 54 may then be accomplished by advancing catheter 10 through the vasculature to a position near embolic protection device 54 (for example, as shown in Figure 1). Once located near embolic protection device 54, inner shaft 12 can be shifted from the first position to a second position. Shifting can occur by advancing sheath 14 distally relative to inner shaft 12. Shifting inner shaft 12 to the second position results in sheath 14 moving distally over inner shaft 12 such that tip 36 is disposed a distance proximally of distal end 40 of sheath 14 (as shown in Figure 2).

Because guidewire 24 may be locked relative to inner shaft 12, shifting the position of inner shaft 12 results in shifting of guidewire 24 relative to sheath 15. In general, when inner shaft 12 shifts to the second position, guidewire 24 shifts such that it becomes disposed near proximal end 46 of opening. Because embolic protection device 54 is coupled to guidewire 24, shifting inner shaft 12 to the second position results in sheath 14 passing distally over at least a portion of embolic protection device 54 (as shown in Figure 2). When at least a portion of embolic protection device 54 is disposed

within sheath 14, catheter 10 (and, thus, embolic protection device 54) may be removed from the vasculature.

Catheter 10 may also be used to deliver embolic protection device 54. For example, inner shaft 12 may be in the second position (as shown in Figure 2) and advanced through the vasculature. While advancing, embolic protection device 54 may be at least partially collapsed within sheath 14. Upon reaching a desired location, sheath 14 may be shifted (in the proximal direction) relative to inner shaft 12 and guidewire 24 such that embolic protection device 54 emerges from distal end 40 of sheath 14. Generally, embolic protection device 54 is designed to be self-expanding such that when device 54 emerges from sheath 14 it assumes the expanded configuration appropriate for filtering embolic debris. Thus, the shift of sheath 14 in the proximal direction allows embolic protection device 54 to expand and be delivered. Once embolic protection device 54 is delivered, catheter 10 may be removed from the vasculature.

Figure 2 is a cross sectional view of a filter retrieval catheter in an arrangement suitable for removal from the vasculature. Inner shaft 12 can be shifted from the first position to a second position relative to outer sheath 14 as shown. In the second position tip 36 may be substantially contained within lumen 42 of outer sheath 14. In addition, a portion of embolic protection device 54 may be disposed within outer sheath 14 after shifting from the first position to the second position. Shifting results in inner shaft 12 (specifically proximal region 28 and/or port 34) becoming disposed near proximal region 46 of opening 44. Subsequent to shifting, guidewire 24 may be secured in place during relative to sheath 14 and both can be removed proximally from the patient's vasculature.

Figure 3 is a side view of an alternate embodiment of an outer sheath further comprising a cover sheath. A cover sheath 56 may be disposed on outer sheath 14 over opening 44. Cover sheath 56 may be comprised of a number of materials including polymers. Alternatively, cover sheath 56 may be comprised of materials similar to those listed above.

Cover sheath 56 may be coupled to outer sheath 14 in a number of differing manners. For example, cover sheath 56 may be coupled to outer sheath 14 by an adhesive. Alternative methods for coupling cover sheath 56 would be familiar to those of ordinary skill in the art.

Figure 4 is a top view of the cover sheath according an embodiment. Cover sheath 56 can further comprise a slot 58. Slot 58 may be sized appropriately for passage of guidewire 24. In addition, slot 58 may be substantially self-resealing. Self-resealing is understood to mean that slot 58 essentially prevents the passage of fluids therethrough but allows guidewire 24 to be moveable therein.

Figure 5 is a cross sectional view for preparation of a filter retrieval catheter according to an embodiment of the invention. Preparation of filter retrieval catheter 10 may include the step of substantially eliminating of air from vacant space 60 within inner shaft 12. Air may be substantially eliminated from vacant space 60 by flushing vacant space 60 with a fluid, such as saline. Alternative flushing mediums may be used without departing from the spirit of the invention.

To prepare filter retrieval catheter 10, fluid may be flushed through distal region 30 of tubular member 26 and throughout tubular member 26. Fluid can be additionally

flushed through proximal end 38 of outer sheath 14, distal end 40 of outer sheath 14, and through opening 44. Flushing substantially eliminates air from vacant space 60.

Figure 6 is a cross sectional view for preparation of a filter retrieval catheter according to an embodiment of the invention. In addition to vacant spaces 60, distant vacant spaces 62 may be present. According to some embodiments of the invention, distant vacant spaces 62 may not be adequately flushed by the using the preparation strategy shown in Figure 5.

To address this issue, an alternate filter retrieval catheter 110 may be constructed including an alternate inner shaft 112. Inner shaft 112 may comprise tubular member 126. Tubular member 126 can further comprise a plurality of flush holes 164. According to this embodiment, flushing fluid through inner shaft 112 and through tubular member 126 may result in substantial flushing of distant vacant spaces 62 by allowing fluid to be flushed through holes 164.

It should be understood that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.